	TES DISTRICT COURT N DISTRICT OF MISSISSIPP
ESTATE OF DORIS BURNETT, DECEASED, By and Through the Administratrix MONIQUE BURNETT, Plaintiff	DAVID CREWS, CLERK Deputy
VS.	Case No. 4:08CV26-P.B
PFIZER, INC.	JURY TRIAL DEMANDED

COMPLAINT

Plaintiff, Estate of Doris Burnett, Deceased, by and through the undersigned attorney files causes of action against defendants, as follows:

PARTIES

- 1. Plaintiff Estate of Doris Burnett, Deceased, ("plaintiff") brings this action through its Administratrix Monique Burnett.
- 2. Plaintiff is the surviving daughter of decedent Doris Burnett ("decedent").

 As such she is a proper party under Mississippi's wrongful death statute to bring a cause of action on behalf of all the persons entitled to bring an action for the wrongful death of decedent.
- 3. On September 9, 2004 plaintiff was appointed as Administratrix of the Estate of Doris Monique in the Chancery Court of Bolivar County, Second Judicial District, Mississippi. A copy of the Order Granting Letters of Administration is attached hereto as Exhibit "A". As such, she is a proper party to pursue a survival action on behalf of decedent.
- 4. At the time of the negligent acts complained of herein and at all times mentioned, plaintiff has been an individual over the age of 21 years old, residing in Bolivar County, Mississippi.

- 5. Defendant Pfizer, Inc. ("Pfizer" and/or "defendant") is a Delaware corporation with its principal place of business in New York. Pfizer and can be served Pfizer, Inc. and can be served with process at Pfizer, Inc., Attention: Legal Department 235 East 42nd Street, New York, New York 10017.
- 6. At all relevant times, defendant Pfizer designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed Bextra throughout the United States.
- 7. Upon information and belief, Pharmacia & Upjohn Company ("Pharmacia"), is owned and/or a subsidiary and/or agent of Defendant Pfizer, Inc.
- 8. At all relevant times, Pharmacia designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed the drug Valdecoxib under the brand name Bextra ("Bextra" or the "drug") throughout the United States. Defendant Pfizer is liable for the conduct and negligent/gross negligent of Pharmacia & Upjohn Company.
- 9. G.D. Searle, LLC ("Searle") is owned and/or a subsidiary and/or agent of Defendant Pfizer, Inc.
- 10. At all relevant times, Searle designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed Bextra throughout the United States. Pfizer is liable for the conduct and negligent/gross negligent of Pharmacia & Upjohn Company.
- 11. Upon information and belief, as the result of a corporate merger between Pfizer,

Pharmacia and Searle on or about April 16, 2003, Pharmacia and Searle became wholly-owned subsidiaries of Pfizer. As a result thereof, Pfizer is legally responsible for all obligations, debts and liabilities of Pharmacia and Searle and is the successor in interest and real party to Pharmacia and Searle (collectively "Pfizer" and/or "defendants").

JURISDICTION AND VENUE

- 12. Plaintiff seeks in excess of \$75,000, excluding costs and interests. This Court has jurisdiction of this matter under 28 U.S.C 1332.
- 13. Venue is proper in this District pursuant to 28 U.S.C 1391.

STATEMENT OF FACTS

- 14. Decedent was prescribed and ingested Bextra between June 10, 2003 and December 19, 2003 and she died on January 8, 2004 as a result of a sudden heart attack.
- 15. Bextra is the brand name of Valdecoxib, one of a class of drugs called "prostaglandins," which is used to reduce inflammation and pain by providing analgesic and anti-inflammatory benefits to persons with, among other conditions, osteoarthritis, rheumatoid arthritis and dysmenorrheal (menstrual pain). Prostaglandins are COX (cycloxygenase) inhibitors. COX enzymes metabolize arachidonicacid to produce prostaglandins.
- 16. Bextra is a COX-2 inhibitor, which is designed to produce prostaglandins at inflammatory sites, and to produce prostacyclin, a vasodilator and an inhibitor of platelet aggregation.
- 17. On November 16, 2001, Valdecoxib was approved by the FDA for relief of symptoms of osteoarthritis and adult rheumatoid arthritis.
- 18. In the first coronary artery bypass grafting (CABG) study, the study found that

there was a statistically significant increase in thromboembolic events (myocardial infarction, cerebrovascular accident, deep vein thrombosis and pulmonary embolism) in the group treated with Parecoxib/Valdecoxib post-p as compared to the placebo group.

19. Parecoxib is an intravenous COX-2 inhibitor which the body metabolizes to the active form, Valdecoxib (Bextra). However, the FDA rejected Parecoxib when it came up for approval.

- 20. Although Parecoxib is effective as an analgesic only when it is converted to Valdecoxib in vivo, and approval of Valdecoxib was based on studies in patients with low cardiovascular risk, the labeling of Valdecoxib does not reflect the experience with Parecoxib.
- 21. On November 5, 2004, Pfizer submitted the final report of the second CABG study to the FDA, which included over 1,500 patients treated after CABG. This report showed an increased cardiovascular risk in patients treated with Bextra compared to placebo. Observed cardiovascular events included thromboembolic events such as myocardial infarction, cerebrovascular accident, deep vein thrombosis and pulmonary embolism.
- 22. As discussed more fully above, a series of clinical and epidemiologic analyses have raised questions about the cardiovascular safety of all coxibs, all of which were available to defendants during their marketing of Bextra.
- 23. On December 9, 2004, defendants Pfizer, Pharmacia and Searle finally acknowledged the increased risk of heart attack associated with Bextra and strengthened the label by adding a "bolded warning."
- 24. At or about the same time, Garrett Fitzgerald, M.D. of the University of

Pennsylvania pooled data of other COX-2 inhibitor drug use in 5,930 patients participating in 12 clinical trials. Among all the patients, Dr. Fitzgerald says the risk for heart attacks and strokes was more than twice as high in those taking COX-2 inhibitors compared with people who took placebos.

- 25. Defendants' clinical and epidemiological studies were intentionally and/or negligently designed so that one could not detect an increased risk of cardiovascular events in patients who did not have CABG, however epidermiological studies, as well as the pharmacological mechanism of action and injury of Bextra, all conclusively showed, by the time of Bextra's launch, that it presented an unreasonable cardiovascular risk to patients.
- 26. Despite the foregoing, defendants continue to represent to consumers that Bextra is safe, and that any cardiovascular and/or cardiothrombic side effects are not associated with the drug.
- 27. Defendants either directly or through its agents, servants, and employees, designed, manufactured, marketed, advertised, distributed, and sold Bextra for the treatment of osteoarthritis, rheumatoid arthritis and pain and other "off-label" uses.
- 28. As a result of the defective nature of Bextra as well as defendants failure to warn of the increased cardiovascular risk, those persons who were prescribed and ingested or injected Bextra, including decedent, have suffered severe and permanent injuries.
- 29. Defendants concealed their knowledge of Bextra's unreasonably dangerous risks from decedent, other consumers, and the medical communities.
- 30. Defendants failed to conduct adequate post-marketing surveillance of Bextra, after they began marketing, advertising, distributing and selling the product.

- 31. On April 7, 2005, the Food and Drug Administration announced that it had asked Pfizer, Inc. to withdraw Bextra. Had defendants properly disclosed the risks associated with using Bextra, decedent would not have taken the drug.
- 32. As a direct and proximate result of decedent's ingestion of Bextra, decedent suffered a heart attack and died on January 8, 2004.
- 33. Defendants acted in a willful, wanton, and/or fraudulent manner toward decedent and other Bextra consumers, and plaintiff is therefore entitled to punitive damages.

COUNT I

STRICT LIABILITY

- 34. Plaintiff incorporates by reference the allegations in the above paragraphs.
- 35. Defendants were engaged in the business of manufacturing, designing, testing, marketing, selling, advertising, warning, and distributing Bextra. The Bextra consumed by decedent reached decedent without substantial change in the condition in which it was sold by defendants.
- 36. Decedent used Bextra in the manner for which it was intended and a manner which was reasonably foreseeable.
- 37. Decedent was not aware of, nor could she have discovered, the dangerous nature of Bextra.
- 38. The Bextra consumed by decedent was in a defective condition and unreasonably dangerous in that it was defective in design, manufacturing, instructions and/or warnings to doctors, the FDA, and the consuming public, and such defects existed at the time the Bextra was sold by defendants.
- 39. The actions of defendants caused or contributed to cause the pain, suffering, and death of decedent.

- 40. As a direct and proximate result of the defects in Bextra, decedent sustained damages including but not limited to severe injury to her body, severe pain and suffering, mental anguish, loss of enjoyment of life and death.
- 41. As a direct and proximate result of the defects in Bextra, plaintiff has incurred funeral expenses, and has and will continue to suffer mental anguish, suffering, bereavement, loss of companionship, comfort, care and support that would have been provided her but for defendants' negligence.
- 42. The aggravating circumstances attending decedent's death and the wanton conduct of defendants as set forth above entitle plaintiff to an award of punitive damages.

WHEREFORE, plaintiff demands judgment against defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all other such relief as the Court deems proper.

COUNT II

NEGLIGENCE

- 43. Plaintiff incorporates by reference the allegations in the above paragraphs.
- 44. Defendants had a duty to use reasonable care in the manufacturing, design, testing, marketing, warning, and advertising of its product Bextra.
- 45. Defendants were negligent and breached their duty of reasonable care in that Defendants:
- a. Failed to adequately and properly test Bextra so as to ascertain whether or not it was safe and proper for the purpose for which it was designed, manufactured and sold;
- b. Failed to utilize and/or implement a reasonably safe design in the manufacture of Bextra;
- c. Failed to manufacture Bextra in a reasonably safe condition for which it was intended:

- d. Failed to adequately and properly warn doctors, the FDA, and the consuming public regarding the risks of complications in using Bextra in a manner for which it was intended;
- e. Failed to adequately and properly label Bextra so as to warn doctors and the consuming public of the risks of complications in using Bextra; and
- f. Failed to adequately and properly label Bextra so as to warn plaintiff and doctors of the risk of heart attack and stroke with the use of Bextra;
- 46. The actions of defendants caused of contributed to cause the pain, suffering, and death of decedent.
- 47. As a direct and proximate result of the defects in Bextra, decedent sustained damages including but not limited to severe injury to her body, severe pain and suffering, mental anguish, loss of enjoyment of life and death.
- 48. As a direct and proximate result of the defects in Bextra, plaintiff has incurred funeral expenses, and has and will continue to suffer mental anguish, suffering, bereavement, loss of companionship, comfort, care and support that would have been provided her but for defendants' negligence.
- 49. The aggravating circumstances attending decedent's death and the wanton conduct of Defendants as set forth above entitle plaintiff to an award of punitive damages.

WHEREFORE, plaintiff demands judgment against defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III NEGLIGENCE PER SE

- 50. Plaintiff incorporates by reference the allegations in the above paragraphs.
- 51. Defendants had an obligation to comply with the law in the manufacture, design,

- testing, production, research, distribution, marketing, labeling, and warning of the risks and dangers of Bextra.
- 52. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq., related amendments and codes of federal regulations provided thereunder, the Sherman Food, Drug and Cosmetic Law, and other applicable laws, statutes and regulations.
- 53. Decedent, as a purchaser and consumer of Bextra, is within the class of persons the statutes and regulations described above are designed to protect and decedent's injuries are the type of harm these statutes are designed to prevent.
- 54. Defendants' actions constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §331 and constitute a breach of duty subjecting defendants to civil liability for all damages arising therefrom.
- 55. Defendants failed to meet the standard of care set by the following statute and regulations, which were intended for the benefit of individuals such as decedent, making defendant negligent per se:
- a. The labeling lacked adequate information on the use of the drug Bextra (21 C.F.R. §201.56(a) and (d));
- b. The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitation, thromboembolic events, primarily heart attacks or stroke, and other adverse medical conditions, as soon as there was reasonable evidence of their association with the drug (21 C.F.R. §201.57(e));
- c. There was inadequate information for patients for the safe and effective use of Bextra (21 C.F.R. §201.57(f)(2));
- d. There was inadequate information regarding special care to be exercised by the doctor for safe and effective use of Defendants's drug Bextra (21 C.F.R. $\S 201.57(f)(1)$); and

- e. The labeling was misleading and promotional (21 C.F.R. §201.56(b)).
- 56. Defendants' violations of the statutes described above, caused or contributed to cause the pain, suffering, and death of decedent.
- 57. As a direct and proximate result of the defects in Bextra, decedent sustained damages including but not limited to severe injury to her body, severe pain and suffering, mental anguish, loss of enjoyment of life and death.
- 58. As a direct and proximate result of the defects in Bextra, plaintiff has incurred funeral expenses, and has and will continue to suffer mental anguish, suffering, bereavement, loss of companionship, comfort, care and support that would have been provided her but for defendants' negligence.
- 59. The aggravating circumstances attending decedent's death and the wanton conduct of defendants as set forth above entitle plaintiff to an award of punitive damages.

WHEREFORE, plaintiff demands judgment against defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV BREACH OF EXPRESSWARRANTY

- 60. Plaintiff incorporates by reference the allegations in the above paragraphs.
- 61. Defendants expressly warranted to decedent, by and through statements made through authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Bextra was safe, effective, and fit and proper for its intended use.
- 62. In using Bextra, decedent relied on the skill, judgment, representations and

foregoing expressed warranties made by defendants. Said warranties and representations were false in that Bextra was not safe and was unfit for the use for which it was intended.

63. The actions of defendants caused of contributed to cause the pain, suffering, and

- 64. As a direct and proximate result of the defects in Bextra, decedent sustained damages including but not limited to severe injury to her body, severe pain and suffering, mental anguish, loss of enjoyment of life and death.
- 65. As a direct and proximate result of the defects in Bextra, plaintiff has incurred funeral expenses, and has and will continue to suffer mental anguish, suffering, bereavement, loss of companionship, comfort, care and support that would have been provided her but for defendants' negligence.

WHEREFORE, plaintiff demands judgment against defendants for compensatory damages, together with interest, costs of suit, attorneys' fees and such other relief as the Court deems proper.

COUNT V

BREACH OF IMPLIEDWARRANTY

66. Plaintiff incorporates by reference the above paragraphs.

death of decedent.

- 67. Prior to the time that Bextra was used by plaintiff, defendants impliedly warranted to decedent that Bextra was of merchantable quality and safe and fit for the use for which it was intended.
- 68. Decedent was unskilled in the research, design and manufacture of Bextra and reasonably relied entirely on the skill, judgment and implied warranty of defendants in using Bextra.
- 69. Bextra was neither safe for its intended use nor of merchantable quality in that it

had dangerous propensities when put to its intended use and would cause injuries to the

user.

70. The actions of defendants caused of contributed to cause the pain, suffering, and

death of decedent.

71. As a direct and proximate result of the defects in Bextra, decedent sustained

damages including but not limited to severe injury to her body, severe pain and suffering,

mental anguish, loss of enjoyment of life and death.

72. As a direct and proximate result of the defects in Bextra, plaintiff has incurred

funeral expenses, and has and will continue to suffer mental anguish, suffering,

bereavement, loss of companionship, comfort, care and support that would have been

provided her but for defendants' negligence.

WHEREFORE, plaintiff demands judgment against defendants for compensatory

damages, together with interest, costs of suit, attorneys' fees and all other such relief as

the Court deems proper.

JURY TRIAL REQUEST

73. Plaintiff requests a jury trial.

Respectfully submitted,

Jun Boone 11 3/3/08

Leyi Boone, III, Esq.

BOONE LAW FIRM, P.A.

401 West Sunflower Road Cleveland, Mississippi 38732

ATTORNEY FOR PLAINTIFF

IN THE CHANCERY COURT OF THE SECOND JUDICIAL DISTRICT OF BOLIVAR COUNTY, MISSISSIPPI

IN THE MATTER OF THE ESTATE OF: DORIS BURNETT, DECEASED

CIVIL ACTION NO.

MONIQUE BURNETT

PETITIONER

ORDER GRANTING LETTERS OF ADMINISTRATION

This day this cause came on to be heard on the duly verified petition of Monique Burnett seeking to be appointed administratrix of the Estate of Doris Burnett, deceased and for letters administration with respect to the Estate of Doris Burnett, deceased and the Court having duly and maturely considered the same and the evidence having first found that it has jurisdiction of the parties and the subject matter and full authority to grant relief prayed for, and having found that each and every matter, statement of fact and allegation set forth in the petition to be fully substantiated by the proof and to be true and correct as therein stated, and the Court otherwise being fully advised in the premises, does accordingly: Order and Adjudge as follows:

- 1. Doris Burnett departed this life on January 8, 2004 and had at the time of her death a fixed place of residence in Cleveland, Second Judicial District of Bolivar County, Mississippi.
- 2. Doris Burnett had no Last Will and Testament, so far as petitioner knows or believes after a diligent search and inquiry.
- 3. Doris Burnett left surviving her the following heirs at law and wrongful death beneficiaries: Monique Burnett, daughter, an adult resident citizen of Cleveland, Second Judicial District of Bolivar County, Mississippi; and Desmond Burnett, son, an adult resident

citizen of Cleveland, Second Judicial District of Bolivar County, Mississippi.

- 4. Petitioner would show that the estate should be immediately administered for the proper management thereof and for the prompt collection of the assets. The estate consists of no real or personal property. Upon information and belief, the death of Doris Burnett may have been caused by the negligence of certain medical providers and petitioner seeks to investigate and determine the cause of death.
- 5. Petitioner is over the age of eighteen (18) years, is of sound mind and has not been convicted of a felony.
- 6. It would be in the best interest of the Estate that petitioner, Monique Burnett, daughter of the decedent, be granted letters of administration. This Court waive on the necessity of posting a bond in the premises pending further order.

IT IS THEREFORE ORDERED AND ADJUDGED that:

- 1. Monique Burnett is hereby appointed to serve as administratrix of the Estate of Doris Burnett, deceased.
- 2. The Clerk of the Court is hereby directed to issue to Monique Burnett letters of administration upon her taking the oath required by law and the necessity of filing a bond is hereby waived.

CHANCELLOR CHANCELLOR

*JS 44 (Rev. 12/67) a 6 20 20 20 30 40 78

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

the civil docket sheet. (SEE I	INSTRUCTIONS ON THE REVERSE OF THE FORM.)					
I. (a) PLAINTIFFS			DEFENDANTS			
Estate of Doris Burnett, Deceased, By and Through the Administratrix, Monique Burnett		8	Pfizer, Inc.			
(b) County of Residence of First Listed Plaintiff Bolivar (EXCEPT IN U.S. PLAINTIFF CASES)			County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.			
(2)						
Levi Boone, III, Esq., Bo	e, Address, and Telephone Number) Oone Law Firm, P.A.		Attorneys (If Known)			
P. O. Box 1772, Clevela	and, MS 38732 Ph. 662-843-7946					
II. BASIS OF JURISI	DICTION (Place an "X" in One Box Only)			RINCIPAL PARTIES	(Place an "X" in One Box for Plaintiff	
☐ 1 U.S. Government Plaintiff	☐ 3 Federal Question (U.S. Government Not a Party)		(For Diversity Cases Only) Plan of This State			
2 U.S. Government Defendant	M 4 Diversity	Citize	en of Another State	2		
	(Indicate Citizenship of Parties in Item III)		en or Subject of a	_	1 6 1 6	
IV. NATURE OF SUI	T (Place an "X" in One Box Only)	1 Foi	eign Country			
CONTRACT	TORTS		RECEIVED	BANKRUPTCY	OTHER STATUTES	
☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment	Slander 368 Asbestos Persona Injury Product Liability Liability PERSONAL PROPER 370 Other Fraud 370 Other Fersonal 350 Motor Vehicle Product Liability 380 Other Personal Product Liability 385 Property Damage Product Liability 360 Other Personal Product Liability 385 Property Damage Product Liability S70 Other Personal Product Liability PRISONER PETITIO S10 Motions to Vaca Sentence Habeas Corpus: S30 General S35 Death Penalty S40 Mandamus & Other Penalty S40 Mandamus & Other Penalty S50 Civil Rights	-	0 Agriculture 0 Other Food & Drug 5 Drug Related Scizure of Property 21 USC 881 0 Liquor Laws 0 R.R. & Truck 0 Airline Regs. 0 Occupational Safety/Health 0 Other LABOR 0 Fair Labor Standards Act 0 Labor/Mgmt. Relations 0 Labor/Mgmt. Reporting & Disclosure Act 0 Railway Labor Act 0 Other Labor Litigation 1 Empl. Ret. Inc. Security Act IMMIGRATION 2 Naturalization Application 3 Habeas Corpus -	□ 422 Appeal 28 USC 158 □ 423 Withdrawal 28 USC 157 PROPERTY RIGHTS □ 820 Copyrights □ 840 Trademark SOCIAL SECURITY □ 861 HIA (1395ff) □ 862 Black Lung (923) □ 863 DIWC/DIWW (405(g)) □ 864 SSID Title XVI □ 865 RSI (405(g)) FEDERAL TAX SUTS □ 870 Taxes (U.S. Plaintiff or Defendant) □ 871 IRS—Third Party 26 USC 7609	400 State Reapportionment 410 Antitrust 430 Banks and Banking 450 Commerce 460 Deportation 470 Racketeer Influenced and Corrupt Organizations 480 Consumer Credit 490 Cable/Sat TV 810 Selective Service 850 Securities/Commodities/Exchange 875 Customer Challenge 12 USC 3410 890 Other Statutory Actions 891 Agricultural Acts 892 Economic Stabilization Act 893 Environmental Matters 894 Energy Allocation Act 990 Appeal of Fee Determination	
V. ORIGIN (Place	Other 440 Other Civil Rights		Alien Detainee 5 Other Immigration Actions		950 Constitutionality of State Statutes	
⊠ 1 Original 2 Re	tate Court Appellate Court	Reop	ened anothe	erred from district Grant Gran		
VI. CAUSE OF ACTI	ON Cite the U.S. Civil Statute under which you a 28 U.S.C. 1332 Brief description of cause: Wrongful death-product liability of		** * * * * * * * * * * * * * * * * * * *	i statutės uniess diversity):		
VII. REQUESTED IN COMPLAINT:				F. &d CHECK YES only JURY DEMAND:	-	
VIII. RELATED CAS IF ANY	SE(S) (See instructions): JUDGE			DOCKET NUMBER		
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FOR OFFICE USE ONLY	$\overline{}$		-/-/		,	
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